

(15)

# AUSTRALIAN PATENT OFFICE

## SEARCH REPORT

Applicant's or agent's file reference <b>6525SG60/KJR/SEL/HBA</b>		
Application No. <b>SG 200800359-2</b>	Application Filing Date ( <i>day/month/year</i> ) <b>18 July 2006</b>	(Earliest) Priority Date ( <i>day/month/year</i> ) <b>18 July 2005</b>
Applicant <b>PROTALIX LTD. (IL)</b>		

This search report consists of a total of **5** sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. ☐ Certain claims were found unsearchable (See Box I)

2. ☒ Unity of invention is lacking (See Box II)

3. ☐ The application contains disclosure of a nucleotide and/or amino acid sequence listing and the search was carried out on the basis of the sequence listing

☐ filed with the application

☐ furnished by the applicant separately from the application,

☐ but not accompanied by a statement to the effect that it did not include matter going beyond the disclosure in application as filed



\*172172\*

4. With regard to the title, ☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Office to read as follows:



5. With regard to the abstract, ☒ the text is approved as submitted by the applicant

☐ the text has been established by this Office as it appears in Box III

\*G00002\*

6. The figure of the drawings to be published with the abstract is Figure No.

☐ as suggested by the applicant.

☐ because the applicant failed to suggest a figure

☐ because this figure better characterises the invention

☒ None of the figures

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Application No.

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SG 200800359-2

### Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This search report has not been established in respect of certain claims for the following reasons:

1. ☐ Claims Nos.

because they relate to non-patentable subject matter (sections 13 and 16) not required to be searched by this Office, namely:

2. ☐ Claims Nos.

because they relate to parts of the application that does not comply with the prescribed requirements (sections 25(4) and 25(5)) to such an extent that no meaningful search can be carried out, specifically:

### Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This Office found multiple inventions in this application, as follows:

The international application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept.

Note that Rule 13.2 states that where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only where there is a technical relationship among those inventions involving one or more of the same corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

In assessing whether there is more than one invention in the claims, I have given consideration to those features which can be considered to potentially distinguish the claimed combination of features from the prior art. Where different claims have different distinguishing features they define different inventions.

*Continued in Supplemental Box 1*

☒ Accordingly, this Office is reporting only on the main invention of claims 1-19, 31, 35-73 and 85-88 partially and claims 20 and 74 entirely.

☐ Since little extra effort was involved, this Office is reporting on the inventions of claims

**SUPPLEMENTAL BOX 1**  
**CONTINUATION OF BOX: II**

The following 12 inventions have been identified.

Invention 1: Claims 1-19, 31, 35-73 and 85-88 partially insofar as they relate to VP2 of IBDV and claims 20 and 74 entirely.

Invention 2: Claims 1-19, 31, 35-73 and 85-88 partially insofar as they relate to Human interferon  $\beta$  and claims 21 and 75 entirely.

Invention 3: Claims 1-19, 31, 35-73 and 85-88 partially insofar as they relate to Human clotting factor and claims 22 and 76 entirely.

Invention 4: Claims 1-19, 31, 35-73 and 85-88 partially insofar as they relate to Human factor X and claims 23 and 77 entirely.

Invention 5: Claims 1-19, 31, 35-73 and 85-88 partially insofar as they relate to high mannose protein and claim 24 and 84 entirely.

Invention 6: Claims 1-19, 31, 35-73 and 85-88 partially insofar as they relate to human lysosomal enzyme and claims 25 and 78 entirely.

Invention 7: Claims 1-19, 31, 35-73 and 85-88 partially insofar as they relate to human glucocerebrosidase and claims 26, 27, 32-34, 79 and 80 entirely.

Invention 8: Claims 1-19, 31, 35-73 and 85-88 partially insofar as they relate to growth hormone and claims 28 and 81 entirely.

Invention 9: Claims 1-19, 31, 35-73 and 85-88 partially insofar as they relate to FSH and claims 29 and 82 entirely.

Invention 10: Claims 1-19, 31, 35-73 and 85-88 partially insofar as they relate to acetyl choline esterase and claims 30 and 83 entirely.

The only feature common to inventions 1-12 is that they relate to the use of plant cells in the manufacture of medicament for oral or mucosal administration where the plant cells are capable of expressing a biologically active recombinant biomolecules.

Given that plant cells are capable of expressing a biologically active recombinant biomolecules that can be used as a medicament are known, and their use in pharmaceutical compositions is well documented as disclosed in the following documents, this feature cannot be considered as a unifying 'special technical feature'. It follows that claims 1 to 88 do not relate to one invention only *a posteriori*.

US 2002/0015708 A1 (STRAM, Y. et al) 07 February 2002

WO 2003/013598 A2 (DOMINIC. L., et al) 20 February 2003

GIDDINGS *et al*; (2000), Nature Biotechnology, Vol 18, No 11, pages 1151-1155; "Transgenic plants as factories for biopharmaceuticals".

Therefore this search report is restricted to Invention 1 including claims 1-19, 31, 35-73 and 85-88 partially as they relate to VP2 of IBDV and claims 20 and 74 entirely.

**AUSTRALIAN PATENT OFFICE**  
**SEARCH REPORT**

Application No.  
SG 200800359-2

**A. CLASSIFICATION OF SUBJECT MATTER**

According to International Patent Classification (IPC)

Int. Cl.

A61K 39/12 (2006.01)

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the search (name of data base and, where practicable, search terms used)

EPODOC, BIOSIS, MEDLINE, CHEM ABS (plant, biopharmaceuticals, IBDV, VP1, VP2)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2002/0015708 A1 (STRAM, Y. et al) 07 February 2002 ([0019], [0020], [0024], [0025], Example 2, Claims)	1-9, 12, 14, 17-20, 31, 35-38, 41-53, 55-64, 66-68, 71, 74 and 85-88
X	WO 2003/013598 A2 (LAM, D.M.K., et al) 20 February 2003 (page 13-15, 23-26, 57)	1-20, 31, 35-74 and 85-88



Further documents are listed in the continuation of Box C



See patent family annex

\* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of submission of the request to the Australian Patent Office

20 October 2008

Date of completion of the search report

10 December 2008

Date of mailing of the search report

23 DEC 2008

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**AUSTRALIAN PATENT OFFICE****SEARCH REPORT****PATENT FAMILY MEMBERS**

Application No.

SG 200800359-2

Patent Document Cited in Search Report		Patent Family Member	
US	2002015708	US	6528063
WO	2003013598	NONE	
Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.			
END OF ANNEX			